

# NAVIGATE®

*Steering you through the design  
and development process*



Seafaring has shaped our world and the history of mankind like no other field of exploration. From the discovery of the Americas to navigating the North West Passage and races at speed across the world's oceans, each have pushed the limits of human and engineering capabilities. It is this same vision, this desire to conquer the unknown that drives the Freudenberg Medical Navigate® team. With our passion, commitment and expertise we will help you steer a course that will open a world of possibilities.

## WHAT IS NAVIGATE®?

Navigate® is a unique Freudenberg Medical programme to drive innovation and speed through our customers' design process. Our team of professional medical device engineers have a proven track record in charting the course of new product development through the most testing and extreme conditions.

We invite you to explore this technology and the expertise housed in our Navigate® centre to support and accelerate your next product launch.

## OUR LOCATION

Situated in Galway, Ireland, on Europe's most westerly shoreline we are inspired by a proud history in maritime achievement. We operate from a state of the art product research and development laboratory equipped with dedicated manufacturing and test equipment.

## OUR SERVICES

- Design for Manufacture & Assembly (DFMA)
- Materials analysis
- Advanced materials selection & development
- Fluoropolymer coatings development
- Project management
- Project costing
- Failure Mode & Effect Analysis (FMEA)
- Dedicated manufacturing & test equipment for prototyping
- Process development & validation
- Biocompatibility testing



## HOW THE NAVIGATE® DESIGN & DEVELOPMENT PROCESS WORKS

### Idea Generation

We begin by 'laying-out' the ideas which have been explored. This evaluation is led by our engineering team and often involves face-to-face meetings with our customers to gain a complete understanding of the project. Ideas that have failed are identified along with the reasons for their failure. Some ideas may be noted for their contribution to the project and retained for further investigation.

Building on the advances already made, our team begins the process of developing new ideas. Drawing on their extensive experience in the field of medical device engineering our team will develop credible alternatives. Working closely with our customers through this research and testing phase we ensure there is a good flow of information in both directions. The protection of our customers' intellectual property is a high priority, and we always endeavour to steer away from areas of sensitivity.

### Concept Testing

Ideas will be assessed on their merits and potential to be successfully advanced through each development stage right through to launch. Prototypes may be produced at this stage to test basic functionality for some deliverables. We encourage our customers to visit our facility at this point so that they can be on hand to make minor adjustments to the concept ideas. This is normally carried out in a day with the support of our Navigate® team.

### Prototype Development

Following rigorous testing, we typically will have uncovered several ideas that we can now progress through to the next development phases. Before we proceed further, we include our operations teams in the Navigate® process to assess the manufacturability of the product ideas. Their engagement at an early stage ensures that there will be a smooth transition to manufacturing later, saving time and cost. All equipment used at this point is mirrored in production so that validations will be able to rely on data captured at the prototype stage.

### Design for Manufacture

The input of our operations team ensures that product solutions can be manufactured efficiently and effectively at scale. Navigate® team members have all worked in operations and understand what can and cannot be done. We employ the simple philosophy "to generate the best possible methods in the least overall time." This stage can be cyclical and may require compromises to develop the most cost-effective solutions.

### Validation

Once the method of manufacture has been agreed with our customer input, we continue the validation of the product through our processes. Our internal risk analysis and validation procedures will identify any areas of concern that are then addressed with input from the customer.

The timeline here is shortened due to the earlier evaluative work. In addition, the equipment used has been previously validated and therefore much of the framework and risk analysis has been undertaken.

### Launch

All steps in this process can be treated as stand-alone services or a complete project deliverable from the Navigate® Team. The output from the previous steps can be a comprehensive report for a regulatory body right through to a completed assembly. With an unwavering commitment to both the project and our customers, we steer a course through all challenges and strive to deliver results that exceed our customer's expectations.

### Do you have any questions?

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